DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Honorable Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

SEP 16 2003

Re: FDA Docket 00N-1571
In the matter of: Enrofloxacin for Poultry: Withdrawal of Approval of Bayer Corporation's New Animal Drug Application 140-828 (Baytril)

Dear Judge Davidson:

The Animal Health Institute (AHI) has filed, under section 515 of the Treasury and General Government Appropriations Act for FiscalYear 2001, an information quality complaint with respect to a *Campylobacter* risk assessment prepared by the Food and Drug Administration's (FDA's or agency's) Center for Veterinary Medicine (CVM). As you know, CVM has relied, in part, on this risk assessment in the above-captioned formal evidentiary hearing over which you are presiding (under 21 C.F.R Part 12).

As you are aware, due to mandated separation of functions that must be followed during a Part 12 hearing, the Commissioner and Deputy Commissioner are recused from any activity involving this stage of the administrative hearing. As Principal Associate Commissioner, I have been delegated the authority to act as the Commissioner on this matter until such time as the Commissioner or Deputy Commissioner is no longer recused.

The Office of Management and Budget (OMB) has issued guidelines implementing section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001. 67 F.R. 8452 (Feb. 22, 2002). OMB's guidelines state that the administrative mechanisms allowing affected persons to seek correction of information disseminated by a federal agency should be flexible and incorporated into the agency's administrative practices. In the preamble to its guidelines, OMB recognized that many agencies already have processes in place to respond to public concerns and stated that it was not its intent to require these agencies to establish new processes. 67 F.R. at 8458.

As directed by OMB's guidelines, FDA and HHS have issued information quality guidelines to help ensure and maximize the quality, objectivity, utility, and integrity of information disseminated by the agency. http://www.hhs.gov/infoquality/part1A-9-20.htm; http://www.hhs.gov/infoquality/fda.html. Like OMB's guidelines, FDA's guidance provides that the agency intends to use existing processes to address

complaints from the public concerning its information dissemination activities. The guidance lists a variety of procedures already in place to address complaints from the public, including public comment procedures for rulemakings and other formal agency actions. These procedures provide well-established procedural safeguards that allow affected persons to raise information quality issues on a timely basis. Accordingly, as provided in the guidance, FDA intends to use these existing procedures to respond to information quality complaints that arise in these contexts.

By utilizing these existing procedures, such as an on-going Part 12 hearing, FDA will be able to avoid the potential for having two different parts of the agency evaluating the same issue and arriving at differing conclusions.

As you know, the formal evidentiary hearing over which you are presiding on the agency's proposal to withdraw approval of the new animal drug application for enrofloxacin (Baytril, NADA 140-828) is a formal agency action. This hearing should provide well-established procedural safeguards allowing affected persons to raise information quality issues on a timely basis. Accordingly, in my capacity acting for the Commissioner in this matter, I have determined on behalf of the agency that, in addition to considering any other issues raised with respect to the risk assessment in the on-going formal evidentiary hearing under 21 C.F.R. Part 12, you should evaluate the risk assessment under section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001, in accordance with OMB, HHS, and FDA guidelines.

I appreciate your handling this issue.

Sincerely,

Murray M. Lumpkin

Murray M. Lumpkin, M.D., M.Sc.
Principal Associate Commissioner

cc: Kent D. McClure, D.V.M., J.D. (Animal Health Institute)
Nadine Steinberg
Counsel for Center for Veterinary Medicine